Confusion between methylphenidate and methadone

Problem: The Food & Drug Administration has received six medication error reports involving cases of inadvertent administration of methadone with various methylphenidate products. Four of the error reports involved cases of inadvertent administration of methadone (10-mg oral tablets) rather than the intended Metadate ER (methylphenidate HCl extended-release, 10-mg oral tablets). In addition, two reports involved the inadvertent administration of methadone instead of the intended, unidentified methylphenidate product.

The first generic methadone product was approved in the early 1980s. Methadone is indicated for the relief of severe pain, detoxification treatment of narcotic addiction, and temporary maintenance treatment of narcotic addiction. A methadone product, when used as an analgesic, may be dispensed in any licensed pharmacy. Methadone products, when used for the treatment of narcotic addiction in detoxification or maintenance programs, are to be dispensed only by approved hospital pharmacies, approved community pharmacies, and by FDA- and state-approved maintenance programs.

The agency has approved three Metadate products—all of which are manufactured by Celltech (formerly Medeva)—indicated for the treatment of attention deficit disorders. Metadate ER 20 mg was approved on June 1, 1988, and Metadate ER 10 mg was approved on Oct. 20, 1999. Metadate CD (20 mg) was approved on April 3, 2001.

Of the six medication errors reported to the FDA, four involved prescriptions for Metadate ER that were misinterpreted and dispensed as methadone (see table). At the time these errors occurred, Metadate ER had been approved for at least one year. All four errors, three of which were discovered prior to patient administration, occurred in outpatient settings in children ranging from five to 12 years of age. In only two of the cases, written prescriptions were identified as being part of the error process.

Two additional cases, also reported to the agency, did not specifically identify the type of methylphenidate product involved in the error (see table). One report involved the death of an eight-year-old male patient following a possible medication error at

By
Nora L. Roselle, Pharm.D.
Carol Holquist, R.Ph., and
Jerry Phillips, R.Ph.

MEDWATCH

POSTMARKETING REPORTS OF MEDICATION ERRORS

METADATE ER AND METHADONE

Date of event	Patient age	Intended product	Dispensed product	Outcome	Cause(s)
11-10-00	12 years	Metadate ER 10 mg	Methadone 10 mg	Error detected prior to patient administration	Dispensing error
2-1-01	Seven years	Metadate ER 10 mg (written prescription)	Methadone 10 mg	Error detected prior to patient administration	Dispensing error: due to look-alike and soundalike similarities as well as misreading doctor's handwriting
2-1-02	Five years	Metadate ER 10 mg (written prescription)	Methadone 10 mg	Error detected prior to patient administration	Computer entry and dispensing error
2-11-02 (Report date)	Unknown	Metadate ER 10 mg	Methadone 10 mg	Unknown	Dispensing error

METHYLPHENIDATE AND METHADONE

3-16-95	Unknown	Methylphenidate 5 mg and 10 mg	Methadone 5 mg and 10 mg	Unknown	Dispensing error
1-99 or 2-99	Eight years	Methylphenidate	Methadone	Death	Dispensing error suspected

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the dispensing pharmacy. In this case, the child was being treated for attention deficit disorder with methylphenidate (strength and brand name not identified in the report) and was found dead at home. Methadone substitution was listed as the suspected cause of death. In the second case, a patient had prescriptions for methylphenidate 5 mg and 10 mg, and methadone 5 mg and 10 mg were dispensed in error.

We believe that errors between methadone and Metadate CD have not been reported because methadone is available in both 5-mg and 10-mg strengths, while Metadate CD is available only in a 20-mg strength.

A comparison of the current methadone and Metadate ER product labeling and packaging shows minimal commonalties between the two; therefore, we believe the errors deal more with name confusion. There are many similarities between Metadate ER and methadone that may have aided in the confusion between the two drug products. Both drugs have overlapping dosage forms (tablet), routes of administration (oral), and strengths (10 mg). In addition, Metadate ER and methadone are Schedule II controlled substances that are prescribed several times a day. Methadone, used in the treatment of pain, is usually dosed six to eight times a day, while Metadate ER is often given two to three times a day. Likewise, both names have similar lengths when written (eight vs. nine letters) and have three syllables when spoken. In addition to the mentioned similarities, poor handwriting may also increase the risk of confusion and error.

Recommendation: One way to help prevent this type of error is to separate methylphenidate products from methadone products if they are stored in close proximity to one another on the pharmacy shelf or in a locked vault. When double-checking prescriptions, pharmacists should verify the age of the patient against what is being prescribed. This is especially important for controlled substances, which can have serious adverse effects in pediatric populations. Prescribers can also help prevent errors by including the indication for use on the prescription order. This may aid the pharmacist in selecting the correct medication, as well as reduce errors due to poor handwriting. Additionally, the FDA would be interested in learning about more of these types of medication errors. Medication errors may be reported through the FDA MedWatch Adverse Event Reporting System at *http://www.fda.gov/medwatch/.*

Nora Roselle, Pharm.D., is safety evaluator; Carol Holquist, R.Ph., is deputy director; and Jerry Phillips, R.Ph., is director, Division of Medication Errors & Technical Support, Office of Drug Safety, Food & Drug Administration.